In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

* *		
JAMES HARVEY, M.D.,	*	
	*	No. 20-596V
	*	Special Master Christian J. Moran
Petitioner,	*	
v.	*	
	*	Filed: March 18, 2025
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* *		

Jessica A. Wallace, Siri & Glimstad LLP, Aventura, FL, for Petitioner;
Ryan D. Pyles, United States Dep't of Justice, Washington, D.C., for Respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

James Harvey alleges that an influenza ("flu") vaccine caused him to suffer leukocytoclastic vasculitis and post-vaccine polyneuritis. Pet., filed May 13, 2020. The Secretary disputes Dr. Harvey's entitlement to compensation. Both parties have supported their positions with reports from expert witnesses and argued through memorandum.

A review of the evidence and arguments shows that Dr. Harvey is not entitled to compensation. This denial of entitlement is based upon a failure to establish with preponderant evidence that the flu vaccine caused the vasculitis.

[1] Because this decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

Another challenging issue, which is not resolved, is whether the vasculitis caused a polyneuropathy. The reasoning is set forth below.

I. Facts

A. Before Vaccination

Dr. Harvey was born in 1941. He had worked as a cardiothoracic surgeon but had retired from practicing medicine before he received the allegedly causal flu vaccination. Exhibit 1 (aff.) ¶ 4.

Decades before the vaccination, Dr. Harvey developed asthma. Exhibit 15 at 50 (Sep. 5, 2017 record stating that Dr. Harvey "had onset of his asthma when he was 36 years old"); Exhibit 13 at 389 (Sep. 17, 2019 record stating that Dr. Harvey "developed asthma 42 years ago"). Asthma is a recurring problem for Dr. Harvey.

Around the age of 64 years old (or approximately 2005), Dr. Harvey was diagnosed with diabetes. Exhibit 21 at 14-16 (July 7, 2015). In a July 7, 2015 appointment with an endocrinologist, Dr. Harvey denied numbness and tingling in his feet. Id. In the next two years before the vaccination, Dr. Harvey had annual appointments with his endocrinologist. Id. at 10-13 (Mar. 18, 2016) and 6 (Mar. 29, 2017).

In 2016, Dr. Harvey had a shunt placed to treat normal pressure hydrocephalus ("NPH"). Exhibit 8 at 36. "Hydrocephalus" is "a condition marked by dilation of the cerebral ventricles, most often occurring secondary to obstruction of the cerebrospinal pathways . . . and accompanied by accumulation of cerebrospinal fluid within the skull." Dorland's Illus. Med. Dictionary 867. "Normal pressure hydrocephalus" often presents as "dementia, ataxia, and urinary incontinence with hydrocephalus . . . occurring in middle-aged and older persons. The cerebrospinal and spinal fluid pressures are at the upper end of normal, but with excess spinal fluid volume, that pressure is actually abnormally high." Id. At the time of this examination (June 16, 2016), Dr. Harvey complained about unsteady gait, forgetfulness, and urinary urgency/frequency. Exhibit 8 at 36. The doctor noted that over the past year severe asthma attacks required Dr. Harvey to take high dose steroids. Id.

In the months before the vaccination, Dr. Harvey's asthma was worse than normal. Exhibit 15 at 50 (Sep. 5, 2017). Dr. Harvey reported that although he had required corticosteroids in the spring and fall, he had been off prednisone for six or seven weeks. Id. A pulmonologist at Washington University in St. Louis, Mario

Castro, anticipated that Dr. Harvey would undergo a bronchial thermoplasty. Id. A bronchial thermoplasty is "a procedure healthcare providers use to treat severe asthma. A provider applies heat to the smooth muscles around [the] lungs to shrink them." CLEVELAND CLINIC, *Bronchial Thermoplasty*, https://my.clevelandclinic.org/health/treatments/16811-bronchial-thermoplasty (last visited March 3, 2025). In the three days leading to the bronchial thermoplasty, Dr. Harvey was supposed to take 50 mg of prednisone and then taper the prednisone. Exhibit 15 at 52.

A bronchial thermoplasty was performed on September 19, 2017. Exhibit 15 at 30-31. The taper of prednisone was finished on October 4, 2017. Exhibit 5 at 4.

B. Vaccination and Ensuing Six Months

Dr. Harvey received the allegedly causal flu vaccine on October 6, 2017. Exhibit 3 at 25, 39. The pharmacy where Dr. Harvey received the flu vaccine was in Delaware, near where he lived. Exhibit 1 (aff.) ¶ 6; Pet'r's Br. at 41. Dr. Harvey averred that "[w]ithin several hours after receiving the vaccine, [he] developed a rash all over [his] legs and [he] began to feel down so [he] went to bed and rested." Exhibit 1 (aff.) ¶ 8.

Dr. Harvey's testimony about the rapid onset of symptoms is consistent with a contemporaneously created medical record. Dr. Harvey saw a dermatologist, Kari Boucher, on October 12, 2017, which was six days after the vaccination. Exhibit 5 at 4. Dr. Boucher memorialized a complaint from Dr. Harvey in which Dr. Harvey stated that he had a painful, red, and burning rash for five days. Exhibit 5 at 4. Dr. Boucher diagnosed Dr. Harvey with leukocytoclastic vasculitis. Id. She prescribed a topical cream and prednisone. Id.

Leukocytoclastic Vasculitis

At a simple level, "vasculitis" means "inflammation of a blood or lymph vessel." Dorland's at 1996. In this context, "leukocytoclastic vasculitis" is also known as "hypersensitivity" vasculitis. Id. One type of hypersensitivity vasculitis is known as Henoch-Schönlein purpura. Dorland's at 1533; see also id. at 1996

(under "hypersensitivity vasculitis"); Exhibit 19, tab D (Meiller) at 273;[2] Exhibit 19 at 6-7; Exhibit A at 2.

At a mechanistic level, Henoch-Schönlein purpura is mediated by a component of the adaptive immune system known as immunoglobulin A (usually abbreviated "IgA").[3] Exhibit 19, tab D (Meiller) at 274. Thus, Henoch-Schönlein purpura is sometimes known as "IgA vasculitis." People suffering from Henoch-Schönlein purpura create abnormal IgA. Exhibit A, tab 1 (Oni) at 4.[4]

After the rash and pain persisted, Dr. Harvey sought a review by a second dermatologist, Amy C. Musiek. Exhibit 6 at 10. In conjunction with undergoing a punch biopsy, Dr. Harvey reported that he "received the flu shot on October 6th and then experienced the rash on October 7th." Exhibit 15 at 42 (report dated October 17, 2017). The dermatopathology report from the punch biopsy showed IgA, C3, and fibrinogen depositions "with blood vessel walls in the superficial dermis."[5] Exhibit 15 at 24. Prednisone was continued "at 50mg daily until [Dr. Harvey's] paths/labs return." Exhibit 15 at 43.

Dr. Harvey was hospitalized for a bronchial thermoplasty on October 18, 2017 at Barnes-Jewish Hospital in St. Louis. Exhibit 7 at 315; see also id. at 340 (discharge summary). In this context, an internist, David Pham, memorialized that Dr. Harvey stated his vasculitis was "triggered [secondary to] flu shot, however was only off prednisone for 2 days which appears atypical." Id. at 354. By discharge, Dr. Harvey reported that his "rash improved dramatically with corticosteroids and only persist[ed] in his lower extremities. Id. at 340. Through

[2] María José López Meiller et al., Henoch-Schönlein Purpura in adults, 63 CLINICS 273 (2008); filed as Exhibit 19, tab D.

[3] "Immunoglobulins" "function as antibodies [and are] divided into five classes." Dorland's at 908; accord Exhibit 19, tab B (Duarte) at 1. "IgA" contains two subtypes, known as "IgA1" and "IgA2". See Dorland's at 908.

[4] Louise Oni & Sunil Sampath, Childhood IgA Vasculitis (Henoch Schonlein Purpura) – Advances and Knowledge Gaps, 7 FRONTIERS IN PEDIATRICS 4 (2019); filed as Exhibit A, tab 1.

[5] In this context, "C3" refers to a type of complement. Complement refers to the process by which the body destroys cells to which antibodies are attached. See Dorland's at 387-89. "Fibrinogen" is a substance that assists with coagulation. Dorland's at 667 (under coagulation factor I).

his attorney of record, Dr. Harvey states that his "itchy, red, and burning purpuric rash . . . subsided after a few weeks." Pet'r's Br., filed Apr. 6, 2024, at 54.[6]

Via telephone, Dr. Harvey and his wife consulted an internist at the Cleveland Clinic, Stephen Hayden, M.D. on October 26, 2017. Exhibit 2 at 46. In addition to noting that the punch biopsy showed IgA vasculitis, Dr. Hayden memorialized a series of other problems: "Muscle weakness is a major problem. He has had falls. Has NPH [normal pressure hydrocephalus]. He has not had his shunt checked in a while. May also have neuropathy, steroid induced myopathy etc. He says his renal function is getting worse. Anion gap. Glucose poorly controlled." Id.

A similar list of issues appeared in the October 31, 2017 record that Dr. Hayden generated after an in-person visit at the Cleveland Clinic in Ohio. Exhibit 2 at 50. Dr. Hayden's impressions included severe persistent asthma, IgA mediated leukocytoclastic vasculitis, uncontrolled type 2 diabetes, and generalized muscle weakness. Id. at 53. Dr. Hayden ordered a CT scan to check Dr. Harvey's normal pressure hydrocephalus. This CT scan showed that there was "no significant change since 06/06/2016." Exhibit 2 at 60 (Nov. 1, 2017).

For a check of his diabetes, Dr. Harvey saw an endocrinologist in the Cleveland Clinic, Susan Williams, on November 1, 2017. Exhibit 2 at 68-80. A review of systems included: "FEET: painful with neuropathy" and "NERVOUS SYSTEM: feet are affected." Id. at 69. Dr. Williams conducted a physical exam. She inspected Dr. Harvey's feet and he had "normal distal pulses." Id. at 74. His gait was "flat-footed and awkward [though] stable." Id. She assessed Dr. Harvey as having "Uncontrolled type 2 diabetes mellitus with complication, with long-term current use of insulin." Dr. Williams added that Dr. Harvey's blood sugar widely fluctuated "due to corticosteroids." Id. Dr. Harvey maintains that Dr. Williams did not diagnose him with diabetic neuropathy. See Pet'r's Br. at 46.

Dr. Harvey had a follow up appointment with Dr. Hayden on November 2, 2017. Exhibit 2 at 86-88. Dr. Hayden directed Dr. Harvey to "[c]ontinue prednisone taper. If muscle weakness improves, he may not need further evaluation for that. If it does not improve, I [Dr. Hayden] recommend Neurology/Neuromuscular evaluation with EMG." Id. at 86-87. Dr. Hayden

[6] Due to the resolution of the vasculitis within six months of the vaccination, Dr. Harvey can fulfill the Vaccine Act's severity requirement only if the vasculitis caused a neuropathy. See Pet'r's Br. at 20; Resp't's Br. at 33. The severity issue is discussed, but not resolved, in section V below.

memorialized that Dr. Harvey "would like to postpone further thermoplasty procedures until diabetes is controlled. He has [to] take three days of prednisone 50 mg daily before the procedure, and has increased symptoms [from] the secretions after the procedure, requiring high dose prednisone." Id. at 88.

After this appointment, there appears to be a three-month gap in in-person medical appointments. However, between early November 2017 and early February 2018, Dr. Harvey frequently communicated with doctors via patient portals.

Using the patient portal, Dr. Harvey informed Dr. Hayden that he "remain[ed] very weak" on November 8, 2017. Exhibit 2 at 96. Dr. Harvey was concerned that he was experiencing a steroid myopathy. Accordingly, Dr. Hayden advised that Dr. Harvey could stop prednisone. Id. at 87. A few days later, Dr. Harvey stated that he was improved. Id. at 103 (Nov. 12, 2017). However, ankle and foot pain prompted Dr. Harvey to cancel a third bronchial thermoplasty, which had been scheduled for November 14, 2017. Exhibit 15 at 40.

By November 24, 2017, Dr. Harvey was still feeling weak and was having trouble walking. Thus, he attempted to schedule an appointment with a neurologist whom he had seen at the Cleveland Clinic, Joseph Rudolph, M.D. Exhibit 2 at 116. Due to the need to arrange to travel for this appointment, Dr. Harvey proposed an appointment in February 2018. However, Dr. Rudolph was not available. Id.; see also Exhibit 25 (Dr. Rudolph's affidavit) ¶ 9.

About one week later, Dr. Harvey repeated his attempt to schedule an appointment with Dr. Rudolph for "neuro evaluation, plus myopathy." Exhibit 2 at 124 (Dec. 1, 2017). Yet, Dr. Rudolph remained unavailable. Dr. Harvey made a third attempt but was not successful. Id. at 135 (Dec. 11, 2017).

Finally, Dr. Harvey requested an appointment with another neurologist with expertise in movement disorders. Exhibit 2 at 137 (Dec. 14, 2017). Dr. Harvey eventually saw Dr. Ilia Itin. See Exhibit 1 (aff.); Exhibit 2 at 174.

Before Dr. Harvey got to see Dr. Itin, Dr. Harvey communicated with his primary care physician, Dr. Hayden, through the patient portal and raised the possibility of an adverse reaction to the vaccine. Dr. Harvey wrote: "Might it be a good idea for me to see somebody expert in vaccines? I find it difficult to attribute this problem to prednisone, which I have endured for 40 years, often in higher and lengthy doses? Would m[y] feather sensitivity have cross-over problems with egg vaccines, etc?" Exhibit 2 at 169 (Feb. 8, 2018). Similarly, Dr. Harvey also asked:

"my myopathy in temporal relationship to flu vaccine induced IgA vasculitis…I have lost strength, balance, stamina… Is this a vaccine reaction complex?" Id. at 169 (Feb. 13, 2018).

Dr. Hayden suggested that Dr. Harvey see a doctor in "Neuromuscular Medicine (Neurology) to assess the cause of the muscle weakness." Exhibit 2 at 168. In this context, Dr. Hayden mentioned that he was uncertain whether the weakness was induced by steroids and that Dr. Harvey "questions flu vaccine." Id.

Dr. Harvey returned to his pulmonologist, Dr. Castro, on February 5, 2018. The note from this record states that although Dr. Harvey had been scheduled for a third thermoplasty on November 14, 2017, Dr. Harvey canceled the procedure due to ankle and foot pain. Exhibit 15 at 40.

On February 20, 2018, Dr. Harvey went to the Cleveland Clinic for his appointment with the neurologist, Ilia Itin. Dr. Itin's note is relatively detailed. With respect to events around the vaccination, Dr. Itin wrote:

> Over time, on 10/5/2017 [sic] he had a flu shot. He was weaning off oral steroids (he is asthmatic) when he broke out in rash following flu shot. He was diagnosed with IGA vasculitis which was treated with steroids. The patient feels that his gait deteriorated from that point on[.] [He] was on steroids until 11/2017[;] glucose was elevated[.]"

Exhibit 2 at 174. With respect to more current problems, Dr. Itin stated:

> He has trouble getting out of bed; standing up from the toilet (proximal muscle weakness). The patient has no stamina, he gives out and needs to rest. He is using wheelchair more. He is [cautious] but he never fell. The patient admits memory problems. . . . He admits increased frequency of urination. The shunt was not adjusted for past three years.

Id. at 175. Dr. Itin recommended physical therapy and prescribed a medication for depression, escitalopram. Id. at 178.[7]

[7] Dr. Itin also anticipated that "Dr. Nagel" would assess Dr. Harvey. However, the role of Dr. Nagel is not readily apparent.

An appointment with a physical therapist, Randy Karim, happened on February 20, 2018. Exhibit 2 at 190-91. Dr. Harvey was described as having decreased strength in his hips, decreased range of motion, decreased flexibility, decreased balance, and problems in coordination. Id.

The next day, Dr. Harvey saw his endocrinologist, Dr. Williams. Exhibit 2 at 232 (Feb. 21, 2018). In the context of the history of present illness, Dr. Williams wrote a complication was "peripheral neuropathy." Id. The review of systems stated: "FEET painful with neuropathy" and "NERVOUS SYSTEM: feet are affected." Id. at 233. On physical exam, Dr. Williams found "proximal weakness persists." Id. at 238. Dr. Harvey had a rash on his feet. Dr. Harvey's gait was flat-footed and awkward but stable. Id. at 74, 238. Dr. Harvey again asserts that Dr. Williams did not diagnose him with a neuropathy. Pet'r's Br. at 49.

For follow up of his normal pressure hydrocephalus and check of his shunt, Dr. Harvey went to the University of Pennsylvania where he was seen by Dr. Lucas on March 29, 2018. Exhibit 8 at 41-46. Dr. Lucas memorialized a complaint that Dr. Harvey has "had a rocky year with myalgia, [and] reactions to vaccines." Exhibit 8 at 46. With respect to the shunt, Dr. Lucas examined it and recommended Dr. Harvey return in one year. Id.

C. Remainder of 2018 and 2019

Dr. Harvey informed Dr. Hayden about a communication with Dr. Harvey's previous neurologist, Erwin Montgomery, M.D. Dr. Harvey recounted that Dr. Montgomery

> advised that I should see a neuromuscular neurologist rather than a movement disorders one. Certainly, the guy I saw last time was no help…doing what docs do when they can't help…make the patient a head case. I am NOT depressed nor anxious, and if I were, I'd not hesitate to seek help.

Exhibit 2 at 351 (July 3, 2018).

As to the anti-depressant medication, Dr. Harvey disagreed with this diagnosis and did not fill the prescription. Exhibit 1 (aff.) ¶¶ 20-21; see also Exhibit 2 at 249 (Feb. 22, 2018 email to Dr. Hayden in which Dr. Harvey wrote that he did not need "psych drugs").

A few days later, Dr. Harvey inquired through the patient portal about, among other points, getting the shingles vaccine. Exhibit 2 at 358 (July 7, 2018). Dr. Hayden's response involved the flu vaccine:

> I don't think you should get egg based flu vaccine if that is what caused the previous reaction.
>
> Whether you can or should receive a different flu vaccine is unclear to me. As the efficacy of flu vaccines is not exactly stellar, the risk benefit ratio suggests to me that maybe it is best to avoid them.
>
> Shingrix is recombinant so there is no reason to suppose it will cause a reaction.

Id. at 360.

Dr. Hayden expressed a similar concern about the flu vaccine after Dr. Harvey inquired about getting a prescription for Tamiflu. In prescribing the medication, Dr. Hayden stated: "[p]atient [is] unable to have influenza vaccine because of prior severe reaction." Id. at 387.

Dr. Harvey continued to press a question about the flu vaccine. He emailed Dr. Hayden on October 5, 2018, writing:

> I remain dissatisfied re[garding] my understanding of the myopathy (or neuromuscular symptoms) temporally related to my flu shot of October 5, 2017 [sic, actually October 6, 2017]. I doubt the hypothesis of prednisone related [because] neither dose nor duration were nearly as high as in many intervals of my 41 year history. . . . Is there anybody who can address my concern?

Exhibit 2 at 404. Dr. Hayden answered that he had reviewed case reports in PubMed and stated that it is "plausible that something like myopathy could occur." Exhibit 2 at 403.

Based upon a referral from Dr. Hayden (Exhibit 2 at 416), Dr. Harvey started physical therapy on November 14, 2018. Exhibit 9 at 3. The assessment was "deconditioning after vasculitis/renal failure."

On February 13, 2019, Dr. Harvey sent a communication to Dr. Hayden through the patient portal and again stated:

> I am not satisfied with explanation (or non-explanation) of my myoneural symptoms arising subsequent to flu shot 10/5/17 [sic]. I remain lacking strength, stamina, balance though I have been off prednisone almost a full year. I am better than last year when you had to wheel me around, but quite severely impaired compared to 10/4/17. I hope somebody can clarify what has happened and what to [expect].

Exhibit 10 at 51. Dr. Harvey reiterated this belief that "my severe myopathy is flu shot related," and requested a recommendation for a specialist, such as a clinical immunologist, who might help identify this issue. Id. at 57 (Feb. 25, 2019). Dr. Hayden stated that he did not know how to prove whether the flu shot caused the problem. Id. at 58.

On March 4, 2019, Dr. Harvey returned to the neurologist whom he had previously seen, Dr. Rudolph. This history section reports that Dr. Harvey "cannot walk very far. He has trouble getting up. This seems to have changed immediately after receiving a flu shot – he seems to have developed a myopathy." Exhibit 10 at 61-63. Dr. Rudolph advised that Dr. Harvey's shunt for normal pressure hydrocephalus should be evaluated. Dr. Rudolph also wrote that Dr. Harvey "should be evaluated for post-inflammatory neuropathy or myopathy – this can start with [an] EMG." Id. at 63.

On the same day as the appointment with Dr. Rudolph, Dr. Harvey saw his endocrinologist, Dr. Williams. She wrote that Dr. Harvey "[p]resents in annual follow up for well controlled T2DM [type two diabetes mellitus] Off Steroids. Still frustrated with neuro issues since his flu injection of 2017 with IgA vasculitis -- myopathy/neuropathy." Exhibit 10 at 72. Dr. Williams listed "peripheral neuropathy" as a "complication." Id. at 72. Her assessment included "controlled type 2 diabetes with complication." Id. at 79.

The EMG, which Dr. Rudolph ordered, took place on April 15, 2019. The results were:

> 1. A generalized sensorimotor polyneuropathy, which is predominantly axonal in type, and mild to moderate in

> degree electrically. There is no evidence of a demyelinating polyneuropathy.
>
> 2. A right ulnar neuropathy, affecting predominantly the sensory fibers, likely moderate in degree electrically.
>
> 3. There is no evidence of a generalized myopathy.

Exhibit 2 at 33.

With the EMG completed, Dr. Harvey saw two specialists in neuromuscular disorders at the Cleveland Clinic, Monica Scarsella and Rebecca Kuenzler. Exhibit 10 at 158-76. Part of this note recounts Dr. Harvey's more remote history, starting with the flu vaccination:

> On Oct 5, 2017 [sic] patient got a [] flu shot. This was followed by a rash on his bilateral lower extremities up to his mid shins, as well as severe malaise causing him to be bedbound for days though he denies signs/symptoms of infection that he can recall. A skin biopsy showed IgA vasculitis.
>
> It is unclear when generalized weakness truly began but thinks was sometime in close proximity to flu shot and does not appear to be sudden onset or focal. He now shows dogs as a hobby and used to be able to walk dogs for long distances. Now can only walk few blocks and very slowly.

Id. at 158.

Doctors Scarsella and Kuenzler memorialized Dr. Harvey's current problems:

> He endorses the need to look at his feet while walking, impaired balance, issues with fine motor movements (picking up papers, buttoning his shirt,) memory impairment although only retrieval which he attributes to NPH.
>
> Gets PT 3x/wk although hasn't improved in months.

> No sensory changes, pain, vision, dysphagia, fasciculations, family history of similar problems, myoclonus, triggers, clasp, SOB, CP, palpitations.

Id.

Dr. Scarsella stated that the "EMG today [is] notable for generalized sensorimotor polyneuropathy, as well as right ulnar sensory neuropathy." Id. at 166. She added that the "Time course for patient's symptoms fits in correlation with a post-vaccination polyneuropathy. There are rare reports of vasculitis occurring after vaccination. Additionally, polyneuropathy can occur in correlation with IgA vasculitis, although this is also rare." Id. at 166. Dr. Kuenzler provided a slightly different take. She wrote that the "time course [was] most compatible with post-vaccine autoimmune response causing IgA-related changes in skin and neuropathy." Id. at 167.

The next day, Dr. Harvey saw another specialist in the Cleveland Clinic. Exhibit 10 at 180-91 (Apr. 16, 2019). This time, the specialty was rheumatology. The rheumatologist, Alexandra Villa Forte, M.D., obtained a history that is more or less consistent with the above, including a notation that "Yesterday during neurology appointment he was noted to have sensory changes. EMG consistent with sensorimotor polyneuropathy." Id. at 180.

Dr. Villa Forte's assessment linked Dr. Harvey's problems to the flu vaccine. She wrote:

> Although polyneuropathy can be seen in association with IgA-vasculitis it is extremely rare and it is much more likely that he had the neuropathy as a reaction to the flu vaccine and not as part of a systemic vasculitic syndrome.
>
> The rash has not recurred and he has no other symptoms or signs to suggest chronic or relapsing IgA vasculitis - making it even more suggestive of a vaccine induced reaction.

Id. at 184.

Dr. Villa Forte made several recommendations. She advised that immunosuppressive therapy was not appropriate at this time and that before getting

vaccines, Dr. Harvey should consider getting guidance from an allergist / immunologist.

Via his patient portals, Dr. Harvey informed Dr. Hayden and Dr. Kuenzler that he planned to contact an attorney about a potential vaccine injury. Id. at 200-03 (Apr. 22, 2019). Similarly, on May 14, 2019, Dr. Harvey requested that his neurologist, Dr. Rudolph, clarify the statement from Dr. Itin and state that Dr. Itin reached an improper diagnosis. Id. at 216.

Dr. Rudolph responded, in part: "Both the Neuromuscular specialist and the Rheumatologist that you saw here acknowledge the possibility of a vaccine-induced response. So you have that evidence." Id. at 232. As for Dr. Rudolph's own knowledge, Dr. Rudolph told Dr. Harvey "as we have discussed, I don't know much about vaccine induced anything, and neuropathy as well is not my area of specialization. So I certainly am not aware of vaccine-induced-neuropathy studies, sorry." Exhibit 10 at 228.

Dr. Rudolph electronically signed a letter addressed to Attorney Wallace regarding Dr. Harvey's history. Dr. Rudolph wrote:

> Dr. Harvey is a gentleman who developed Normal Pressure Hydrocephalus a few years ago. It came to the attention of the medical establishment in 2011-2012, and he had a VP shunt placed in March 2012. This was moderately successful.
>
> Then, in 2017, after receiving a flu shot, he started to decline in strength. This began to complicate his ability to ambulate. On evaluation, it was realized that he has sensory loss as well. Ultimately, after further evaluation, it became clear that the new difficulty in walking (and feeling) was due to a peripheral nerve problem. Electrical testing supported this idea. He seems to have developed a neuropathy as a consequence to the receiving the flu shot. This idea is agreed to by a Neuropathy specialist and by a Rheumatologist. This has caused a significant change to his life - he has been unable to walk longer distances including more than half of a block, and so he had to move to a more accessible house (all on one story).

Exhibit 17.

Dr. Harvey consulted an immunologist, David Lang, on September 19, 2019. Exhibit 13 at 389-90. The purposes included to evaluate an adverse reaction to an influenza vaccination in October 2017. Id. at 389. Dr. Lang noted that he did not have the benefit of reviewing all outside records. Nevertheless, Dr. Lang set out a lengthy history based, in part, on some records and on his interview with Dr. Harvey. Dr. Lang stated that Dr. Harvey told him that the rash began 8-10 hours after the vaccination. The remainder of Dr. Lang's history is generally consistent with the events described in medical records created contemporaneously with the events. As part of the plan, Dr. Lang stated, "History furnished today of cutaneous reaction beginning as early as 8 hours after administration of influenza vaccination would be unusual for a vasculitic process." Id. at 395.

Later that day, Dr. Harvey communicated with Dr. Lang via the patient portal. Dr. Harvey asked whether Dr. Lang has experience in the National Vaccine Injury Program. Id. at 418. Dr. Lang answered that he did "not have experience with the National Vaccine Injury Program." Exhibit 13 at 415. A few weeks later, Dr. Harvey again inquired whether Dr. Lang knew "anybody to advise me upon flu shot following polyneuropathy from vaccine reaction?" Id. at 533. A response from someone apparently in Dr. Lang's office was "Despite follow up we have not obtained the records he requested to assist you with this issue." Id.

D. 2020 and More Recently

Although Dr. Harvey submitted medical records created after 2019, (see Exhibit 48), the parties did not refer to any of those medical records in their briefs regarding entitlement. See Pet'r's Br. at 5 (discussing Dr. Lang's September 19, 2019 record); Resp't's Br. at 14 (discussing emails to and from Dr. Lang in December 2019).

II. Procedural History

Represented by Attorney Jessica Wallace, Dr. Harvey sought compensation through the Vaccine Program. Pet., filed Oct. 6, 2017. He periodically submitted medical records and affidavits.

After reviewing this material, the Secretary argued that compensation was not appropriate because Dr. Harvey had not established a prima facie case establishing that his off-Table injuries were caused by the flu vaccine. Resp't's Rep., filed Dec. 16, 2020, at 12-17. The Secretary has also argued the severity requirement has not been established in this case. Id. at 14.

To develop his case, Dr. Harvey retained Dr. M. Eric Gershwin and Dr. Enrique Aradillas to provide expert opinions. Dr. Gershwin's reports are exhibits 19, 22, 26, 27, and 28. Dr. Aradillas's report is exhibit 23. In addition, Dr. Harvey submitted a statement from his treating neurologist, Dr. Rudolph. Exhibit 25.[8]

To counter that evidence, the Secretary presented reports from Dr. Jonathan Miner and Dr. Daniel Feinberg. Dr. Miner's reports are Exhibits A, E, G, and H and Dr. Feinberg's reports are Exhibits C and F.

Once the parties completed the submission of reports, they were directed to argue their cases through memorandum. Order, issued Dec. 21, 2023. As part of that process, a status conference was held on January 17, 2024, to discuss confusing aspects of Dr. Harvey's case.

In due course, Dr. Harvey submitted his primary brief on April 6, 2024 and his reply on September 4, 2024. In between, the Secretary filed his primary brief on June 4, 2024 as well as a notice of supplemental authority on June 11, 2024. In conjunction with these briefs, the parties filed supplemental reports from experts.

With the submission of Dr. Harvey's reply, the case is ready for adjudication. The case can be resolved on the papers without receiving oral testimony. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018). Dr. Harvey has enjoyed a full and fair opportunity to present evidence and argument. See Pet'r's Status Rep., filed July 3, 2023 (declining to present additional expert reports).

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

[8] Attorney Wallace spent approximately five hours writing Dr. Rudolph's affidavit. Pet'r's Mot. for Interim Fees, filed July 16, 2022, Exhibit 1 (timesheets) at 22. Ms. Wallace also spent multiple hours reviewing drafts of expert reports before they were filed.

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

The Vaccine Act requires that petitioners establish five elements. 42 U.S.C. § 300aa–11(c)(1)(A) through (E). Here, two items are disputed: whether Dr. Harvey has established that the flu vaccine caused his vasculitis (causation corresponds to paragraph (C)) and whether Dr. Harvey has established that the vasculitis and any sequella lasted more than six months (severity corresponds to paragraph (D)). These two issues are taken up in Section IV (causation) and Section V (severity) below.

IV. First Issue: Causation

Because the Vaccine Injury Table does not associate the flu vaccine with vasculitis, Dr. Harvey must pursue a claim that the flu vaccine was the cause-in-fact of the vasculitis. See Pet'r's Br. at 12. For causation-in-fact claims, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

A. Althen Prong One – Medical Theory

The portion of Dr. Harvey's brief discussing the medical theory or medical theories to explain how the flu vaccine can cause vasculitis is not a model of clarity. See Pet'r's Br. at 20-26. This is disappointing as Dr. Harvey was given notice that he needed to clarify his theories. The December 21, 2023 order for briefs stated that a review of the expert reports suggested that theory or theories Dr. Harvey was advancing were not explained well. Thus, Dr. Harvey was expected to discuss at the January 17, 2024 status conference "the theory by which the flu vaccine injured [Dr.] Harvey." Order, issued Dec. 21, 2023. Similarly, the briefing order attempted to impose some structure on the forthcoming briefs by stating that "If Mr. Harvey chooses to set out different theories by which the flu

vaccine can cause IgA vasculitis, Mr. Harvey is ordered to identify each theory by number and devote a separate section of the brief to each theory individually." Order, issued Dec. 21, 2023, at 5.

Despite these instructions, Dr. Harvey did not separately enumerate the theory or theories he is advancing to connect the flu vaccine and vasculitis. See Pet'r's Br. at 20-26. To be clear, Dr. Harvey is not being penalized for how his brief is formatted. The problem with Dr. Harvey's brief is that it mentions multiple concepts without really explaining why any of them are sound and reliable. Such an approach is neither advisable nor persuasive. See Baron v. Sec'y of Health & Human Servs., No. 14-341V, 2019 WL 2273484, at *17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019) (petitioners "need to propose something more than taking a vague 'kitchen sink' approach and listing eleven mechanisms that have been previously submitted in the Program for claims of vaccine-caused injury with various degrees of success. Petitioners have listed many possibilities but have not identified a sound and reliable explanation that can be applied to the vaccines and injury in this case").

A close reading of Dr. Harvey's brief suggests that Dr. Harvey is advancing the theory that the flu vaccine caused "abnormal immunological activation," possibly involving "cytokines" and the "complement system." Pet'r's Br. at 21-22. Another idea that is mentioned is "immune complex deposition." Id. at 22.

Neither Dr. Gershwin in his reports nor Dr. Harvey in his briefs have shown why these theories are sound and reliable in the context of Dr. Harvey's case. To start, an assertion that the vaccine caused an "abnormal" activation of the immune system does not meaningfully advance petitioner's prong one burden. A premise to the Vaccine Program is that vaccines are safe for the vast majority of people but some people for unknown reasons experience an adverse reaction. Any adverse reaction is "abnormal" in the sense that the normal response to a vaccination is not adverse. So, an "abnormal immunological activation" does not constitute a "theory" to satisfy prong one. Hennessey v. Sec'y of Health & Hum. Servs., 91 Fed Cl. 126, 135 (2010) ("Accordingly, one of the special master's well-founded concerns with [the expert's] theory was its vagueness. . . . [The expert's] theory is so broad as to be meaningless. . . . Not only was petitioner's medical theory vague, it also lacked support. Understandably, it would be difficult for his theory to be more specific given the paucity of any medical or scientific literature supporting a link between the [] vaccine and [injury]").

The other ideas, such as those involving cytokines, complement, and immune complexes, are potentially valid theories for prong one as abstract

propositions. However, Dr. Harvey has failed to connect these theories to what is known about IgA vasculitis. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Persuasive evidence shows that IgA vasculitis is due, in part, to problems creating immunoglobulin A. See Exhibit A, tab 1 (Oni) at 4. Dr. Harvey has not reliably linked cytokines, complement, and/or immune complexes to defective IgA. Thus, Dr. Harvey has failed to carry his burden regarding Althen prong one.

B. Althen Prong Three – Timing

Althen's third prong requires "a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278. The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

The medically acceptable timeframe depends, at least in part, on the theory being offered. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013). Any theory that Dr. Harvey could propose is limited by the sequence of events in that the vasculitis appeared within 24 hours of the flu vaccination. See Pet'r's Br. at 51 (acknowledging that "the onset of Dr. Harvey's symptoms occurred within twenty-four (24) hours of his Flu Vaccine").

The rheumatologist whom the Secretary retained, Dr. Miner, persuasively explained that the medically acceptable timeframe for IgA vasculitis exceeds one day and is more likely at least three days. Exhibit G at 2.[9] Dr. Miner based his

[9] Dr. Miner appears to have a greater amount of experience in researching causes of vasculitis than Dr. Gershwin. See Exhibit A at 1. Recognizing Dr. Miner's greater amount of experience is not the same as stating that Dr. Gershwin has no experience in the field. Although Dr. Gershwin has worked as a rheumatologist for decades and, therefore, treated patients with vasculitis, Dr. Gershwin's interest in research appears to be on topics other than vasculitis. A special master may consider differences in experience when evaluating the relative persuasiveness of experts. See Depena v. Sec'y of Health & Hum. Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

opinion upon observations that that infections occur a few days before IgA vasculitis. See Exhibit G, tab 3 (Bhimma) at 4 (noting that in at least half the children with IgA vasculitis an upper respiratory tract infection preceded the onset of the vasculitis "by 1-3 weeks");[10] Exhibit A, tab 3 (Hwang) at 2 ("HSP is known to occur 3 to 10 days after a preceding infection");[11] Exhibit E, tab 1 (Fraticelli) at 834 ("Vasculitis tends to occur 7-10 days after exposure to a drug or infectious trigger").[12] Dr. Miner's opinion is consistent with the view of one doctor who treated Dr. Harvey. In 2019, an immunologist, Dr. Lang, stated that a "cutaneous reaction beginning as early as 8 hours after administration of influenza vaccination would be unusual for a vasculitic process." Exhibit 13 at 395. These articles, Dr. Lang's statement, and Dr. Miner's opinion are a reliable basis for finding that the medically appropriate interval is at least three days after exposure to the triggering infection or agent.[13]

By way of contrast, Dr. Gershwin's opinion that a flu vaccine can cause IgA vasculitis to occur within one day lacks reliability, is poorly explained, and is not persuasively supported by any medical or scientific articles. See Exhibit 19 at 5. Dr. Gershwin appears to assume that before Dr. Harvey received the flu vaccine,

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[10] Rajendra Bhimma, IgA Vasculitis (Henoch-Schonlein Purpura), Medscape (June 28, 2023), https://emedicine.medscape.com/article/984105-overview?form=fpf; filed as Exhibit G, tab 3.

[11] Hyun Ho Hwang et al., Analysis of seasonal tendencies in pediatric Henöch-Schonlein purpura and comparison with outbreak of infectious diseases, 97 MEDICINE 2 (2018); filed as Exhibit A, tab 3.

[12] Paolo Fraticelli et al., Diagnosis and management of leukocytoclastic vasculitis, 16 INTERNAL AND EMERGENCY MEDICINE 834 (2021); filed as Exhibit E, tab 1.

[13] The Secretary also cites a case in which Dr. Gershwin relied upon an article stating, "the temporal relationship between a vaccine and a 'vaccine induced vasculitis is deemed to be in the range of one to six weeks.'" Resp't's Br. at 21, quoting Van Dycke v. Sec'y of Health & Hum. Servs., No. 18-106V, 2023 WL 4310701, at *16 (Fed. Cl. Spec. Mstr. Jun. 7, 2023). Dr. Harvey attempts to distinguish that case because Dr. Gershwin made this statement in the context of a different vasculitis, giant cell arteritis. Pet'r's Reply at 6.

For the reasons explained in the text, the medical articles about IgA vasculitis provide a persuasive basis for finding that a medically appropriate interval is at least three days. Thus, resolving whether Dr. Gershwin is consistent in his opinions appears unnecessary. But see K.A. v. Sec'y of Health & Hum. Servs., 164 Fed. Cl. 98, 116 (2022) ("Repeat experts who have testified or submitted expert reports regularly in a particular field have to live with, or explain away, their previous testimony and their previously filed expert reports"), aff'd without op., 2024 WL 2012526 (Fed. Cir. 2024).

"IgA was already there." Id.[14] Dr. Gershwin has not justified this assumption. For these reasons, Dr. Harvey has not met his burden of proof regarding Althen prong three.[15]

C. Althen Prong Two – Logical Sequence

Given that Dr. Harvey did not present a persuasive medical theory explaining how the flu vaccine can cause IgA vasculitis and given that he did not establish that his vasculitis arose in a time suggestive of causation, it also follows as a matter of logic that Dr. Harvey has not presented a logical sequence of cause and effect. See Stricker, 170 Fed. Cl. 701, 721-22 (2024) ("there is no need to address petitioner's contention regarding the second Althen prong because it is not logically possible to prevail if a claim is rejected on the first prong"); Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012). However, this element is discussed further for sake of completeness.

The remaining Althen prong requires a preponderant presentation of "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, the bulk of Dr. Harvey's argument under the prong 2 heading recites a chronology of some of his medical appointments. See Pet'r's Br. at 40-44.[16] This presentation is not necessarily wrong. It is just incomplete. As the Secretary

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[14] Also citing page 5 of Dr. Gershwin's first report, Dr. Harvey asserts that "the complement is already fixed to the blood vessel." Pet'r's Br. at 52. However, Dr. Gershwin did not assert here that complement was already present.

[15] Furthermore, if Dr. Harvey did have IgA attached to his blood vessels before the vaccination, then, arguably, he was suffering from IgA vasculitis before the vaccination. In this situation, Dr. Harvey could not prevail upon a theory that the vaccine caused the IgA vasculitis. See Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1380-81 (Fed. Cir. 2012); Rocha v. Sec'y of Health & Hum. Servs., No. 16-241V, 2024 WL 752787, at *33 (Fed. Cl. Spec. Mstr. Feb. 1, 2024) (discussing that onset of a disease can precede detection of a disease and citing cases).

[16] A second portion addresses Dr. Harvey's diabetes and the opinion of the Secretary's expert, Dr. Feinberg, that this pre-existing problem caused any neurologic problem. Pet'r's Br. at 44-51. How diabetes affected Dr. Harvey's health is discussed in the context of severity.

argues, a showing that a vaccine can cause a particular injury and the injury developed within an appropriate time does not necessarily carry a petitioner's burden on prong two. Resp't's Br. at 28, citing Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1366 (Fed. Cir. 2012), and Capizzano, 440 F.3d at 1326-27.

A stronger argument with respect to prong two might draw upon statements from treating doctors. Of the various treaters, a few commented upon whether the flu vaccine caused Dr. Harvey. These include the people listed in the following chart.[17]

Date	Doctor	Notes	Cite
10/12/2017	Dr. Kari Boucher (dermatologist)	Memorialized a complaint from Dr. Harvey that he had a painful, red, and burning rash for five days.	Exhibit 5 at 4.
10/17/2017	Dr. Amy Musiek (dermatologist)	Reported that he received the flu shot and experienced a rash the next day.	Exhibit 15 at 42 and 24.
10/18/2017	Dr. David Pham (internist)	Memorialized that Dr. Harvey stated his vasculitis was triggered secondary to flu shot; however, he was only off prednisone for two days, which appeared atypical.	Exhibit 7 at 315, 340, and 354.
2/3/2018	Dr. Stephen Hayden (primary care physician)	Suggested Dr. Harvey see a neuromuscular medicine doctor because Dr. Hayden was uncertain whether weakness was induced by steroids and that Dr. Harvey "questions flu vaccine."	Exhibit 2 at 168-169.
2/20/2018	Dr. Ilia Itin (neurologist)	Memorialized that after weaning off oral steroids, Dr. Harvey broke out in	Ex 2 at 174-175, 178.

[17] The "Notes" column is intended to highlight key information. Additional context can be found in recitation of facts.

Date	Doctor	Notes	Cite
		a rash after the flu shot. He was diagnosed with IgA vasculitis.	
3/29/2018	Dr. Timothy Harris Lucas (neurosurgeon)	Memorialized that Dr. Harvey "had a rocky year with myalgia [and] reactions to vaccines."	Exhibit 8 at 46.
7/7/2018	Dr. Stephen Hayden	After Dr. Harvey inquired about the shingles vaccine, Dr. Hayden recommended that Dr. Harvey should not "get egg based flu vaccine if that is what caused the previous reaction." Dr. Hayden was unsure if Dr. Harvey should receive a different flu vaccine.	Exhibit 2 at 360.
9/6/2018	Dr. Stephen Hayden	Prescribed Tamiflu to Dr. Harvey and stated that Dr. Harvey is "unable to have influenza vaccine because of prior severe reaction."	Exhibit 2 at 387
10/9/2018	Dr. Stephen Hayden	Reviewed PubMed regarding flu vaccine and myopathy and stated that "It seems plausible that something like a myopathy could occur." Note: Dr. Harvey is not alleging the flu vaccine caused a myopathy. See Exhibit 23 at 1 (Dr. Aradillas explaining that Dr. Harvey did not suffer a myopathy).	Exhibit 2 at 403.
2/27/2019	Dr. Stephen Hayden	Stated that "I do not know how to prove the flu shot caused the problem."	Exhibit 10 at 58.
4/15/2019	Dr. Rebecca Kuenzler (neuromuscular specialist)	Memorialized that Dr. Harvey got a flu shot on October 5, 2017 [sic] and reported that it "is unclear when generalized weakness truly began but	Exhibit 10 at 158.

Date	Doctor	Notes	Cite
		thinks was sometime in close proximity to flu shot"	
4/15/2019	Dr. Monica Scarsella (vascular neurologist)	Noted that the time "course for patient's symptoms fits in correlation with a post-vaccination polyneuropathy. There are rare reports of vasculitis occurring after vaccination. Additionally, polyneuropathy can occur in correlation with IgA vasculitis, although this is also rare."	Exhibit 10 at 166.
4/16/2019	Dr. Alexandra Villa Forte (rheumatologist)	Noted that although polyneuropathy can be seen in association with IgA-vasculitis, it is extremely rare and much more likely that Dr. Harvey had the neuropathy as a reaction to the flu vaccine and not as part of a systemic vasculitic syndrome. Note: as explained below, Dr. Harvey is not claiming that the flu vaccine directly caused a neuropathy.	Exhibit 10 at 184.
5/24/2019	Dr. Joseph Rudolph (neurologist)	Responded to Dr. Harvey's inquiry that "Both the Neuromuscular specialist and the Rheumatologist . . . acknowledge the possibility of a vaccine-induced response. So you have that evidence."	Exhibit 10 at 232.
7/26/2019	Dr. Joseph Rudolph	Wrote a letter to Dr. Harvey's attorney that "He seems to have developed a neuropathy as a consequence to the receiving the flu shot." Note: as explained below, Dr. Harvey is not claiming that the flu vaccine directly caused a neuropathy.	Exhibit 17.

Date	Doctor	Notes	Cite
9/17/2019	Dr. David Lang (allergist and immunologist)	Noted that "reaction beginning as early as 8 hours after administration of influenza vaccination would be unusual for a vasculitic process."	Exhibit 13 at 395.
12/17/2019	Dr. David Lang's office staff, Lisa Krueger	Responded to Dr. Harvey that "Despite follow up we have not obtained the records he requested to assist you with this issue."	Exhibit 13 at 533.

In reviewing the comments from treating doctors, it is important to remember that Dr. Harvey is claiming that the flu vaccine caused him to suffer vasculitis and a sequella to the vasculitis is neuropathy. See Pet'r's Br. at 18 (introducing the argument how the flu vaccine can cause IgA vasculitis), 54 (discussing sequella); Pet'r's Reply at 1 (arguing that preponderant evidence shows the flu vaccine caused Dr. Harvey's "injuries including IgA Vasculitis with resulting polyneuropathy"). The arguments presented in Dr. Harvey's memoranda track the opinions presented by his primary expert, Dr. Gershwin. See Exhibit 19 at 4 ("At issue herein is whether an influenza vaccine . . . was a factor in the development of his HSP variation of leukocytoclastic vasculitis that resulted in the residual sequela of post-vaccine polyneuropathy"). Thus, statements that the flu vaccine caused Dr. Harvey to suffer a neuropathy are off target.[18]

Another unusual aspect to the chronology of medical appointments is that often the association between the flu vaccine and vasculitis was reported by Dr. Harvey, and not independent opinions offered spontaneously by his treating physicians. Dr. Harvey's initiation of conversations about the potential for a vaccine to have harmed him is especially apparent in communications with Dr. Hayden.

[18] The Secretary interpreted Dr. Harvey as presenting a claim that the flu vaccine caused IgA vasculitis and the vasculitis caused the neuropathy. See Resp't's Br. at 23 (discussing Althen prong one) and 33 (discussing sequella). Because Dr. Harvey did not assert the theory that the flu vaccine directly caused a neuropathy, this decision does not address that question. See Vaccine Rule 8(f)(1).

In responding to Dr. Harvey's questions about how the flu vaccine harmed him, Dr. Hayden's answers changed. At first, Dr. Hayden noted the question but seemed not to answer it. Exhibit 2 at 168-69. Then, Dr. Hayden recommended avoiding flu vaccines based on eggs but tolerating other flu vaccines. Id. at 358. Around the same time, Dr. Hayden prescribed Tamiflu because Dr. Harvey's "prior severe reaction" prevented him from being vaccinated. Id. at 387-94. Recommendations to avoid certain vaccines have been credited and have not been credited as indications of a causal role for a vaccine. See, e.g., Compare Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) (stating given the testimony of a treating doctor, "the decision to withhold future administration of the pertussis vaccine provides little probative evidence of causation"); Gramza v. Sec'y of Health & Hum. Servs., 139 Fed. Cl. 309, 335-36 (2018) (ruling that the special master was not arbitrary in refraining from giving decisive weight to a note from a treating doctor advising "no future vaccination" when the treater wrote the note three years after the incident); and Bangerter v. Sec'y of Health & Hum. Servs., No. 14-1187V, 2022 WL 439535, at *29 (Fed. Cl. Spec. Mstr. Jan. 18, 2022) (although a recommendation to avoid future vaccinations has some value, this evidence does not carry petitioner's burden on prong two when petitioner failed to meet prongs one and three) With Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1377 (Fed. Cir. 2008) (the opinion of a treating doctor to withhold future vaccines can be quite probative); and Robinson v. Sec'y of Health & Hum. Servs., No. 14-952V, 2021 WL 2371721, *1376-77 (Fed. Cl. Spec. Mstr. Apr. 12, 2021) (evidence that treating doctor withheld vaccines helps support prong two).

Whatever value Dr. Harvey might gain from these notes from Dr. Hayden---and Dr. Harvey does not cite them in the context of his prong two argument---seems tempered by Dr. Harvey's later statement that he does not know how to prove the flu vaccine caused a problem. Exhibit 10 at 58-60.

The treating doctor on whom Dr. Harvey relies most heavily is Dr. Kuenzler. See Pet'r's Br. at 43-44; Pet'r's Reply at 3-4. Certainly, her statement "Time course for patient's symptoms fits in correlation with a postvaccination polyneuropathy. There are rare reports of vasculitis occurring after vaccination. Additionally, polyneuropathy can occur in correlation with IgA vasculitis, although this is also rare" (Exhibit 10 at 166) provides some support for Dr. Harvey's claim.

However, Dr. Kuenzler's view is countered by the statement of Dr. Lang. Dr. Lang wrote that: "History furnished today of cutaneous reaction beginning as early as 8 hours after administration of influenza vaccination would be unusual for a vasculitis process." Exhibit 13 at 395. Given that Dr. Lang is an immunologist,

his opinion regarding the time for an adverse reaction to a vaccine is more credible than the opinion of someone, like Dr. Kuenzler, who appears not to specialize in immunology.

Thus, when considered as a whole, the collection of statements from treating doctors do not persuasively show that the flu vaccine caused Dr. Harvey's vasculitis. This finding is reached without considering two other arguments the Secretary presented regarding Althen prong two.

The Secretary's first counterargument seems to be that Dr. Harvey's discontinuance of prednisone two days before the flu vaccination, which is also two days before the onset of the vasculitis, caused the vasculitis. See Resp't's Br. at 29, citing Exhibit A (Dr. Miner's report) at 5 and Exhibit E (Dr. Miner's second report) at 2. This proposition is intriguing but not adequately developed. Moreover, because the Secretary does not bear a burden to explain what caused the illness until a petitioner establishes a prima facie case, this point need not be resolved conclusively.

The Secretary's second counterargument regarding Althen prong two is based upon (a lack of) challenge-rechallenge. In 2019, Dr. Harvey received the "influenza vaccine but in 4 doses of ¼ usual dose each and without adverse effect." Exhibit 10 at 90. The Secretary reasons that the lack of reaction to a flu vaccine in 2019 suggests that Dr. Harvey did not have an adverse reaction in 2017. See Resp't's Br. at 29-30; see also Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1381 (Fed. Cir. 2012) (ruling that the special master was not arbitrary in rejecting causation when after receiving a second dose of the allegedly causative vaccine, petitioner's disease did not flare); Roshoven v. Sec'y of Health & Hum. Servs., No. 14-439V, 2018 WL 1124737, at *21-22 (Fed. Cl. Spec. Mstr. Jan. 11, 2018) (finding that a lack of adverse reaction to a third dose of a vaccine undermined petitioner's claim that the earlier doses harmed her). Again, this argument is intriguing. However, it is not readily apparent that four one-quarter doses would be likely to cause the same adverse reaction as one full-strength dose. This might be the case, but it would probably require testimony from an immunologist, whom the Secretary did not present here.

Any deficiencies in the Secretary's counterarguments do not enrich Dr. Harvey's evidence on Althen prong two. Neither the statements from treating doctors nor the opinions from Dr. Gershwin are sufficient to meet Dr. Harvey's burden to show with preponderant evidence that the flu vaccine was the cause-in-fact of his vasculitis.

D. Summary regarding Causation

To establish the vaccine was the cause-in-fact of an injury, a petitioner must establish three elements. In this case, Dr. Harvey's evidence regarding the first element, a theory, was particularly devoid of persuasiveness. His evidence regarding the third element, an appropriate temporal relationship, was also very weak. Although the evidence on the second element, a logical sequence of cause and effect, was stronger, its comparative "strength" mostly derives from the weakness of the evidence on the other two elements.

For these reasons, Dr. Harvey is not entitled to compensation. As such, evaluating a different element of compensation, the severity of the injury, is not required. However, for sake of completeness, this issue is taken up next.

V. Second Issue: Severity

The fourth statutory element concerns the severity of injury. 42 U.S.C. § 300aa–11(c)(1)(D). Petitioners may meet this element by establishing that their injury lasted more than six months.[19] The failure to establish six months of injury results in a denial of compensation. See Starvridis v. Sec'y of Health & Hum. Servs., No. 07–261V, 2009 WL 3837479, at *4 (Fed. Cl. Spec. Mstr. Oct. 29, 2009); Song v. Sec'y of Health & Hum. Servs., No. 92-279V, 1993 WL 534746 (Fed. Cl. Spec. Mstr. Dec. 15, 1993), mot. for rev. denied, 31 Fed. Cl. 61 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 1994) (table).

Here, Dr. Harvey concedes that the condition he alleges the flu vaccine caused, IgA vasculitis, did not last six months. Pet'r's Br. at 20. Dr. Harvey, therefore, proposes that he meets the six-month requirement because a sequella to the IgA vasculitis, a peripheral neuropathy, continued beyond six months. Pet'r's Br. at 54. The Secretary does not contest that Dr. Harvey suffered a neuropathy. However, the Secretary contends that the neuropathy was more likely due to diabetes and not due to IgA vasculitis. Resp't's Br. at 34, citing Exhibit C (Dr. Feinberg's opinion) at 4.

Numerous problems prevent this issue from being resolved on the papers. If determining whether Dr. Harvey met his burden on severity were needed to resolve

[19] The Vaccine Act also allows a petitioner to receive compensation if either the vaccinee died or the vaccinee underwent a surgical procedure. However, Dr. Harvey did not die and has not undergone a surgery for his reaction to the vaccine.

this case, then additional development, such as extra briefing and/or a hearing would have been conducted. See Vaccine Rule 8(a) (authorizing special masters to determine whether to hold a hearing).

A primary question is when Dr. Harvey's neuropathy began. In this respect, the Secretary's apparent emphasis on the date of the EMG, which detected the neuropathy, seems misplaced. See Resp't's Br. at 18, 36. Although the EMG was conducted about 18 months after the vaccination, the date the polyneuropathy was identified is not the date the polyneuropathy began. See Sparrow, 173 Fed. Cl. 177, 184, (2024) ("medical tests will generally come after symptoms first develop"), appeal docketed, No. 25-1161 (Fed. Cir. Nov. 8, 2024); see also Exhibit H at 2 (Dr. Miner's report asserting that the date of infection, the date of symptoms, and the date of diagnosis can be different in the context of an infection).

While the April 15, 2019 EMG sets the latest date of Dr. Harvey's polyneuropathy, the earliest date is much less clear. The Secretary goes so far as to suggest that Dr. Harvey's complaint of weakness from before the vaccine could have been a manifestation of the start of polyneuropathy. Resp't's Br. at 36.

Dr. Harvey's answer is that the weakness he reported was due to the preceding operation. Exhibit 23 (Dr. Aradillas's report) at 4. But, except for this episode, Dr. Harvey agrees that "weakness was Dr. Harvey's main complaint with regard to neuropathy." Pet'r's Br. at 50.

A further challenge to determining when Dr. Harvey's polyneuropathy began is the lack of findings in reports from doctors who examined Dr. Harvey after the vaccination and before the EMG. For example, in mid-October 2017, Dr. Harvey was hospitalized for a bronchial thermoplasty. Yet, during this stay, Dr. Harvey affirmatively denied any weakness. Exhibit 7 at 456 (Oct. 18, 2017).

Nonetheless, about one week after discharge, Dr. Harvey told Dr. Hayden over the telephone that "Muscle weakness is a major problem. He has had falls." Exhibit 2 at 46 (Oct. 26, 2017). When Dr. Harvey saw Dr. Hayden, Dr. Hayden seemed more concerned about the shunt in Dr. Harvey's brain. But, the CT scan showed no significant change. Exhibit 2 at 60. Thus, the reason for Dr. Harvey's report of generalized muscle weakness appeared undetermined at the end of October 2017.

The Secretary proposed that Dr. Harvey's diabetes, which Dr. Hayden characterized as "uncontrolled" (Exhibit 2 at 53), caused any peripheral

neuropathy. Resp't's Br. at 6, 34. The potential persuasiveness of this argument is diminished because the endocrinologist, Dr. Williams, did not diagnosis a diabetic neuropathy on November 1, 2017. See Exhibit 2 at 68-80; see also Pet'r's Br. at 46; Exhibit 23 at 3 (Dr. Aradillas's report noting that Dr. Harvey was not diagnosed with peripheral neuropathy); Exhibit 26 (Dr. Rudolph's report) ¶ 16 (stating there was no diagnosis of peripheral neuropathy).[20]

Dr. Williams's lack of assessment of a neuropathy, therefore, both helps and hurts Dr. Harvey's efforts to satisfy the six-month requirement. Dr. Williams might undermine the argument that Dr. Harvey suffered from a diabetic neuropathy. But, what does her note signify for any neuropathy? In Dr. Harvey's view, did Dr. Williams miss an opportunity to diagnose her patient with a (non-diabetic) neuropathy?

Answers to these questions are far from clear. In this circumstance, additional development in the form of oral testimony, particularly from Dr. Williams, and/or argument would probably be appropriate. See Vaccine Rule 8(a) (recognizing special master's discretion to conduct hearings).

However, a hearing to determine whether Dr. Harvey satisfies severity would waste scarce judicial resources as any determination in Dr. Harvey's favor would not change the outcome. Dr. Harvey's case falters for failing to establish with persuasive evidence that the flu vaccine was the cause-in-fact of vasculitis.

VI. Conclusion

As evident in medical records, Dr. Harvey has often wondered whether the flu vaccination caused him to develop vasculitis. This potential connection is understandable in the sense that the vasculitis was detected relatively soon after the vaccination. However, a temporal sequence in which one event preceded a second event does not mean that the first event caused the second event. When called upon in this litigation to establish with preponderant evidence that the flu vaccination was the cause-in-fact for his vasculitis, Dr. Harvey did not meet his burden. Therefore, his claim for compensation is denied.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for

[20] Some of these assertions appear inconsistent with notations in Dr. Williams's records that a "complication" for Dr. Harvey was peripheral neuropathy. See, e.g., Exhibit 2 at 68, 232.

review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master